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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| GRACEWAY PHARMACEUTICALS, LLC and 3M INNOVATIVE PROPERTIES COMPANY,<br><br>Plaintiffs,<br>v.<br><br>PERRIGO COMPANY, PERRIGO ISRAEL PHARMACEUTICALS LTD., AND NYCOMED US INC.<br><br>Defendants. | CIVIL ACTION NO. 2:10cv937<br><br>**CONFIEDNTIAL FILED UNDER SEAL** |

**NYCOMED'S MEMORANDUM IN OPPOSITION**
**TO PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER**

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**STATUTES**

## I. INTRODUCTION

No temporary restraining order ("TRO") should be entered to stop the continued manufacture and sale and use by patients of Nycomed's Imiquimod Cream 5% product for at least the following reasons:

-- Graceway Pharmaceuticals, LLC and 3M Innovative Properties Company (collectively "Graceway" or "Plaintiffs") cannot be irreparably harmed by Nycomed's product in any manner that counts here because Graceway does not make, use or sell a product that is claimed in the patent in suit (U.S. Patent No. 7,665,672, or "the '672 patent"). *In re Gabapentin Litig.*, 648 F. Supp. 2d 641, 655 (D.N.J. 2009); *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1046-47 (N.D. Ill. 2003). Graceway's Aldara product for which it claims harm is not covered by the patent in suit. Graceway's Aldara patents have either expired or are not infringed, according to even Graceway. As shown by Graceway's own exhibit, investors were downgrading their analysis of Graceway's value already because of perceived generic competition in February of 2011. (D.I. 17-7, Ex. D, p. 2). Nycomed just acted faster, as Congress encourages, awarding Nycomed the coveted prize of a 180-day exclusivity against other generic competition (21 U.S.C. § 355(j)(5)(D)(i)(IV)) awarded to the first generic to file.

-- Graceway also cannot be irreparably harmed because any alleged harm experienced by Graceway can be adequately remedied at law and compensated for by money damages, including any possible price erosion, precluding the grant of a TRO.

(Spadea ¶¶ 3, 11, 20-22).[1] Graceway recently licensed the patent in suit from 3M, establishing the value of the patent in terms of money.

-- Graceway's over-heated assertions of the importance of Aldara sales, which is not covered by the patent in suit, are irrelevant. Likewise, the assertions of possible bankruptcy are made in one line in a declaration and are not supported by any proof, such as a lack of a line of credit, proof from balance sheets, or proof of no role of 3M, a very large corporation. (Spadea ¶¶ 23,24). Graceway acquired Aldara in 2007 and all of its Aldara patents set to expire by 2011, demonstrating that Graceway never could have expected any long term success for such an unpatented product. (Spadea ¶¶ 3(I), 23-24).

-- Nycomed cannot be deemed to have wronged Graceway or caused it actionable harm for a TRO because the FDA approved Nycomed's product for sale, specifically addressing in writing any patents identified by Graceway as relating to the product. (Klaum Ex. E). Graceway had identified two other patents, but not the patent in suit.

-- Graceway has acted in neither an equitable nor a timely manner because Graceway never notified or warned Nycomed of the patent in suit or the application that led to it before Graceway filed suit. (Klaum ¶ 10). As admitted by Graceway, Nycomed informed Graceway in a letter dated January 10, 2007 that Nycomed was seeking approval to commercially launch its Imiquimod Cream 5% product on February 25, 2010, and Graceway believed that Nycomed would launch on that date, yet Graceway remained silent about the patent and its application for more than three years and filed the Complaint without warning or notice. (DI 1, ¶¶ 50, 51, 65 and 66).

[1] Submitted herewith are the declarations of Christopher H. Spadea, David Klaum, James Romito, Ph.D., Stephen Banker, Ph.D., Anthony Palmieri, III, Ph.D. and Marcus A. Colucci, including exhibits attached to each of the respective declarations.

-- Graceway acted in neither an equitable nor a timely manner when it did not attempt to seek a TRO on February 2, 2010, the date the patent in suit issued, and three weeks before filing the Complaint, because Graceway admitted that at that time, "prior to receiving FDA approval, Nycomed will have engaged in activities in preparation for manufacturing, distributing, offering to sell, selling and importing" the Nycomed product and that "such activities have already infringed" the patent in suit. (DI 1, ¶¶ 67 and 68).

-- Graceway has acted with unclean hands and in an inequitable manner by filing more than 24 different patent applications in the last three months concerning products with similarities to Nycomed's product. (Colucci Ex. 1). Graceway is using the same attorneys from the same law firm that are prosecuting the patent applications to prosecute this action and they are attempting to extract Nycomed's confidential business information concerning Nycomed's business plans, business strategies and product information on a daily basis.

-- Graceway has not acted in an equitable manner and it has violated F.R.C.P. 11 by filing its Complaint without any good faith belief that Nycomed infringed the patent in suit. The claims of the patent in suit require specific testing of Nycomed's product before good faith allegations of infringement can be made.

-- Graceway cannot succeed on the merits because Nycomed's product does not infringe a single claim of the patent in suit.

-- Graceway cannot succeed on the merits because its patent claims are invalid because they are obvious over the prior art under 35 U.S.C. § 103. (Palmieri ¶ 5; Banker ¶¶ 10, 26-33). A prior art article and sales literature teach the use of imiquimod and the oleic acid that Graceway claims is the invention of the patent in suit. (*Id.*).

-- Graceway cannot succeed on the merits because its patent claims are invalid because they lack proper written description and enablement under 35 U.S.C. § 112. (Banker ¶¶ 19-25).

-- The balance of hardships weighs heavily towards denying the relief because the grant of a TRO would deny Nycomed its 180-day exclusivity against competition that was awarded by the FDA and intended by Congress (21 U.S.C. § 355(j)(5)(D)(i)(IV)) to encourage generic competition, and a TRO would significantly harm Nycomed's business and commercial interests. (Klaum ¶¶ 17-21).

-- Graceway's assertions concerning its financial wherewithal establish that it cannot obtain a bond for a TRO. Nycomed's 180-day exclusivity alone [redacted] $[redacted] to Nycomed, an amount which Graceway tacitly admits it cannot obtain a bond. (Klaum ¶ 20).

-- The public interest weighs heavily in denying the relief because a TRO would deny patients their drug, deny patients a more cost-effective drug, diminish the value of developing and selling lower cost generic alternatives, diminish the rewards from competition and raise health care costs. The public also has an interest in patent rights being finite and thus Graceway's rights for relief ended when its '388 patent expired.

Plaintiffs are precluded from and not entitled to obtain a TRO.

## II. FACTUAL BACKGROUND

### A. Graceway Has No Product Covered By The Patent In Suit

On February 25, 2010, the FDA approved Nycomed's abbreviated new drug application "(ANDA") for an imiquimod cream product. (Klaum Ex. E). The FDA granted the approval after reviewing all patents that were identified as corresponding to the product. *Id.* The FDA further granted Nycomed a limited 180-day generic

exclusivity against generic competition as an award for Nycomed filing the first ANDA, , pursuant to 21 U.S.C. § 355(j)(5)(D)(i)(IV). *Id.*

In its Complaint, Graceway seeks relief for infringement of the '672 patent. There is no dispute that Graceway does not make, use or sell any product under this patent.

Graceway sells an imiquimod cream under the name of Aldara. (Banker Ex. E). Graceway also sells another imiquimod cream under the name Zyclara, but only in Canada for the time being. As reported in Plaintiffs' own Exhibit 11, "In hopes of beating generics to the market, Graceway has been feverishly working on a second-generation drug Zyclara, but it is still uncertain as to when FDA approval will take place." (D.I. 17-7, Ex. 11, pp. 1-2). However, neither of these products fall within the claims of the '672 patent.

Graceway had a patent for imiquimod itself, the active agent in the cream, U.S. Patent No. 4,689,338 ("the '338 patent"). (Colucci Ex. 2). That patent expired on February 25, 2010 and it cannot be revived. Graceway also has a patent for imiquimod in a formulation with isostearic acid, U.S. Patent No. 5,238,944 ("the '944 patent"). (Colucci Ex. 3). That patent covers Graceway's product, Aldara. The '944 patent expires on August 24, 2010 and an associated FDA exclusivity expires on February 24, 2011. Thus, on February 24, 2011, anyone is free to make, use and sell generic Aldara and copy it exactly without any blocking patents. Nycomed's product cannot infringe either of these patents because the '338 patent is expired and the '944 patent requires the use of isostearic acid which is not present in Nycomed's product. Graceway concurs that Nycomed does not infringe these Aldara patents.

**B. Graceway Delayed For More Than Three Weeks In Seeking Relief**

Graceway's Complaint made the following assertions that Nycomed relies on to demonstrate what Graceway believed, intended and did (and did not do) in relation to Nycomed's product. These assertions demonstrate that Graceway delayed to its detriment in seeking a TRO despite its knowledge that Nycomed was allegedly infringing the patent in suit since February 2, 2010 when the patent in suit issued. These assertions also prove that Graceway was aware that Nycomed would launch its product on February 25, 2010 when Nycomed would be granted approval to market by the FDA, but that Graceway did nothing to seek emergency TRO relief beforehand:

> 50. On information and belief, by this ANDA filing, Nycomed has evidenced that immediately after approval, it intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of a pharmaceutical cream containing imiquimod and an oleic acid component for topical application to a dermal or mucosal surface for topical delivery of imiquimod to treat, inter alia, actinic keratosis (the "Nycomed Proposed ANDA Product").
>
> 51. By a letter ("the Nycomed Notice Letter") dated January 10,2007, Nycomed informed Graceway that it had filed ANDA No. 78-548 with the FDA under 21 U.S.C. § 3550), containing a certification pursuant to 21 U.S.C. § 3550)(2)(A)(vii)(IV). The Nycomed Notice Letter states that the Nycomed Proposed ANDA Product contains imiquimod and oleic acid.
>
> 63. On information and belief, once Nycomed receives FDA approval for the Nycomed Proposed ANDA Product, Nycomed will infringe one or more claims of the '672 Patent by manufacturing, using, offering for sale, selling and/or importing the Nycomed Proposed ANDA Product in the United States.
>
> 64. Upon information and belief, FDA approval of the Nycomed Proposed ANDA Product is imminent.
>
> 65. On information and belief, the Nycomed Notice Letter evidences Nycomed's intent to market the Nycomed Proposed ANDA Product (its generic imiquimod product) immediately following the effective expiration date [with pediatric exclusivity] of the '338 Patent on February 25, 2010.

66. Upon information and belief, Nycomed sought approval of the Nycomed Proposed ANDA Product from the FDA to immediately commercialize the Nycomed Proposed ANDA Product upon the effective expiration date [with pediatric exclusivity] of the '338 Patent.

67. On information and belief, based on standard industry practice, prior to receiving FDA approval, Nycomed will have engaged in activities in preparation for manufacturing, distributing, offering to sell, selling and importing the Nycomed Proposed ANDA Product in the United States.

68. On information and belief, such activities have already infringed, or imminently will infringe, one or more claims of the '672 Patent.

### C. Graceway Delayed Seeking Relief To Prejudice Nycomed

As demonstrated by Plaintiffs' assertions above, Graceway believed since January 10, 2007 that Nycomed was developing, manufacturing and preparing to market a product with imiquimod and oleic acid. Graceway even unsuccessfully petitioned the FDA – twice – to deny Nycomed approval to sell. (Colucci Exs. 4-7). Yet Graceway never once notified or warned Nycomed of the patent in suit. (Klaum ¶ 10). Instead, Graceway waited until the last minute to spring the patent on Nycomed, with a motion and declarations ready, and never stated that it would seek a TRO even in its complaint, which it has not even served yet.

## III. ANALYSIS

### A. There Is No Emergency Justifying The Extraordinary Remedy Of A Temporary Restraining Order

The standards for a TRO are similar to that applied to an application for a preliminary injunction. "Preliminary injunctions are extraordinary relief that are not routinely granted." *Altana Pharma AG v. Teva Pharm. USA Inc.*, 532 F. Supp. 2d 666, 673 (D.N.J. 2007) (citing *National Steel Car, Ltd. v. Canadian Pacific Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) (in a patent infringement lawsuit, a preliminary injunction is "a drastic and extraordinary remedy")), *aff'd* 566 F.3d 999 (Fed. Cir. 2009).

Furthermore, "[w]hen the preliminary injunction is directed not merely at preserving the status quo but [ ] at providing mandatory relief, the burden on the moving party is particularly heavy." *Port Drivers Federation 18, Inc. v. All Saints Exp., Inc.*, Civ. No. 09-0868 (WHW), 2009 WL 3766094, *2 (D.N.J. Nov. 10, 2009).

"A decision to grant or deny a preliminary injunction is based on the district court's consideration of four factors: '(1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interests.'" *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1357 (Fed. Cir. 2008) (quoting *PHG Tech. LLC v. St. John Cos.*, 1365 F.3d 1361, 1365 (Fed. Cir. 2006).

The Plaintiff (movant) bears the burden to demonstrate that a preliminary injunction should be granted. "Although the Court must generally weigh all four of these factors, 'a movant cannot be granted a preliminary injunction unless it established *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm.'" 532 F. Supp. 2d at 673 (citations omitted) (emphasis in the original).

**B. The Evidence Confirms There Can Be No Irreparable Harm To Plaintiffs**

**1. Plaintiffs Do Not Make Or Sell A Product Covered By The Asserted Patent**

Plaintiffs do not make or sell any product covered by the '672 patent (*i.e.*, Plaintiffs are non-practicing entities). (Banker ¶¶ 17-18). Further, to the best of Nycomed's understanding, Plaintiffs have not taken any steps to make a product that would be covered by the '672 patent (i.e., Plaintiffs have not filed with the FDA a request for an ANDA or new drug application ("NDA")). (Klaum ¶ 14). As non-practicing entities, Plaintiffs cannot show that sales of Nycomed's generic imiquimod cream have

any relevant impact on sales of Plaintiffs' products covered by the '672 patent. Under similar circumstances courts have found that injunctive relief is not warranted. *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1314 (Fed. Cir. 2007) (affirming an order for an on-going royalty rate and denying a permanent injunction because plaintiff was a non-practicing entity that could not suffer irreparable harm); *Excellent Inventions LLC v. FKA Distributing Co.*, Civ. Action No. H-04-4543, 2005 U.S. Dist. LEXIS 36174, at *29 (S.D. Tex. July 15, 2005) (plaintiff made no products covered by patents; thus, it could not show it would suffer any losses that could not be compensated by money damages); *see also, e.g.,* John M. Golden, *'Patent Trolls' and Patent Remedies*, 85 Tex. L. Rev. 2111 (2007); Andrew Beckerman-Rodau, *eBay v. MercExchange*, 547 US. 388 (2006): *A Review of Subsequent Judicial Decisions*, 89 J. Pat. & Trademark Off. Soc'y 631 (2007).

Plaintiffs argue that sales of Nycomed's generic imiquimod cream will harm sales of Plaintiffs' Aldara product. The Aldara product, however, is not covered by the '672 patent. (Banker ¶¶ 17-18). Plaintiffs cannot extend the scope of the '672 patent to cover products that do not embody the alleged invention in the '672 patent. Such attempts by Plaintiffs constitute a form of patent misuse and at the very least cannot support any claim of irreparable harm requiring equitable relief. *In re Gabapentin Litig.*, 648 F. Supp. 2d 641, 655 (D.N.J. 2009) ("Any conduct that effectively extends the patentee's statutory rights with anticompetitive effect can qualify as misuse if the patentee sought to use the patent to secure more protection from competition than patent law intended to provide. ") (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1046-47 (N.D. Ill. 2003)). In *Smithkline Beecham* Judge Posner rejected the very arguments Graceway is now making. 247 F. Supp. 2d at 1046 (sitting by designation)

*aff'd* 365 F.3d 1306 (Fed. Cir. 2004), *vacated en banc on other grounds* 403 F.3d 1328 (Fed. Cir. 2005), *aff'd on other grounds* 403 F.3d 1331 (Fed. Cir. 2008). Judge Posner explained that the "implication of such a complaint would be that patents should last forever and generic equivalents be outlawed." *Id.* (cited with approval in relevant part, *In re Gabapentin Litig.*, 648 F. Supp. 2d at 655 (D.N.J. 2009)).

**2. Damages And Not Injunctive Relief Can Satisfy Any Claims If Plaintiffs Somehow Prevail**

Even if the Court were to extend the scope of the '672 patent to protect competition of Aldara, a product not covered by the '672 patent, any harm suffered can be readily calculated and is not irreparable. (Spadea ¶ 3); *Minnesota Mining and Mfg. Co., v. Alphapharm Pty. Ltd.*, No. Civ. 99-13, 2002 WL 1299996, at * 4 (D. Minn. Mar. 8, 2002) (no irreparable harm where 3M's damages could be calculated). Failure to show irreparable harm, by itself, provides sufficient reason to deny a preliminary injunction.

Aldara is a mature product that has been on the market for 13 years with a well known history of use. (Spadea ¶¶ 12-19). Where a product market is well known, the Feral Circuit has stated that "[i]n light of the structure of the [product] market" calculating damages "would be "a relatively simple task." *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996). Thus, any damages can be calculated and are not irreparable. (Spadea ¶ 3).

Plaintiffs sweeping, unsupported allegations about price undercutting, loss of market share, confusion in the marketplace and damage to business reputation has been rejected by this Court and cannot support a finding of irreparable harm. This Court stated that while "some courts have recognized these types of harms to support preliminary injunctive relief", "[b]oth loss of market and price erosion are economic

harms and are compensable by money damages." *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, Civ. Action No. 05-CV-1887, 2007 U.S. Dist. LEXIS 65792, at *39 (D.N.J. Sep. 6, 2007) (unpublished), *aff'd without opinion* 2008 U.S. App. LEXIS 12299 (Fed. Cir. Jun. 9, 2008). In *Novartis* this Court rejected arguments that loss of market share and price erosion would lead to irreparable harm, stating that, "the court should not be swayed by the fact that money damages may be difficult to calculate: 'neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial.'" 2007 U.S. Dist. LEXIS 65792, at *39 (quoting *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991). This Court noted that "[s]pecifically, ***in the context of generic competition in the pharmaceutical industry***, some courts have held that loss of market share is compensable economic injury." *Id.* (emphasis added).

Further, this Court in *Novartis* rejected arguments regarding price erosion as irreparable injuries, stating that "'historically, pharmaceutical companies have maintained or even increased prices on brand product when faced with generic competition.'" *Id.* at *40; *see also Nutrition 21*, 930 F.2d at 871 (stating that 'speculation that such [market share] losses might occur' is insufficient to justify preliminary injunction).

Indeed, potential sales loss alone during pretrial litigation cannot establish irreparable harm because such a position would require a finding of irreparable harm to every patentee, regardless of the circumstances. *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990). Moreover, merely providing speculative evidence of damaged reputation and goodwill is not adequate to support a claim of irreparable harm. *See Tech-Wear, Inc. v. Acme Laundry Prods., Inc.*, 38 F. Supp. 2d

1147, 1152 (C.D. Cal. 1998) (stating that allegations regarding lost market share and diminished reputation, without supporting facts, are insufficient to establish irreparable harm). Plaintiff's claim for injunctive relief therefore fails.

**3. Graceway's Assertion Of Dire Consequences Does Not Fit The Facts**

Graceway asserts possible bankruptcy. However, this assertion is allegedly supported by just one line in a declaration and no colorable proof. (Spadea ¶¶ 23-24). No line of credit evidence, no proof from balance sheets, and no discussion of the role of 3M, a very large corporation, are provided. (*Cf.* D.I. 17-7, Ex. 11, p. 1 suggesting Graceway has substantial undrawn reserves). And, again, this argument all depends on Aldara, which is not covered by the patent in suit. According to its papers, Graceway was formed in 2006 and it just acquired Aldara in the beginning of 2007. All of its Aldara patents expire in 2011, demonstrating that Graceway never could have expected any long term revenue from this product.

Graceway's Exhibit 11 (D.I. 17-7, Ex. 11, p. 2) reports that Zyclara is Graceway's future, not Aldara or the patent in suit. As reported, their debt shows it is due starting in 2012. *(Id.)* Zyclara, if it replaces Aldara as Graceway intends, should be more than able to take care of that. (Klaum ¶ 17).

Missing evidence from the owner of the patent, 3M (D.I. 1, ¶ 18), is a very large hole in Plaintiffs' motion. 3M could certainly license others the patent and is probably required to indemnify Graceway from any losses caused by the patent (carefully drawn agreements would), yet the Graceway-3M agreement is never addressed, let alone provided. (Spadea ¶¶ 23-24).

**4. Plaintiff Graceway Valued And Purchased The Patents And Product From 3M**

3M has already licensed its patents and intellectual property to Graceway. Even if Graceway were to prevail (which it cannot), any injury suffered by Plaintiffs can be compensable in damages assessed as part of the final judgment in this case. The Federal Circuit has stated that licensing is "incompatible with the emphasis on the right to exclude that is the basis for [irreparable harm] in a proper case." *T.J. Smith & Nephew Ltd. v. Consolidated Med. Equip., Inc.*, 821 F.2d 646, 648 (Fed. Cir. 1987). Therefore, as a matter of law, Plaintiffs will not suffer irreparable injury.

**5. Plaintiffs' Delay In Seeking Relief And Inequitable Conduct Compel Denial Of The Motion**

Graceway has acted in neither an equitable nor a timely manner. It never notified or warned Nycomed of the patent in suit and it failed to move for a TRO in a timely manner. (Klaum ¶ 10). If Graceway were really subject to irreparable harm, it would have taken action years ago and warned Nycomed. It also would have moved for a TRO on February 2, not on March 1, nearly one month later after Nycomed had launched and [redacted]. Klaum Decl.

Plaintiff's delay in seeking a TRO is fatal to its claim of irreparable harm. *See Hart Intercivic Inc. v. Diebold, Inc.*, 2009 WL 324566, at *8 (D. Del. Sept. 30, 2009) (3 week delay precluded preliminary injunction); *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995), 49 F.3d at 1557; *Nutrition 21*, 930 F.2d at 872 (holding that "delay [] for a substantial period of time before seeking a preliminary injunction at least suggests that the status quo does not irreparably damage [the plaintiff]"); *T.J. Smith*, 821 F.2d at 648 ("There is no basis in this record for application of a presumption of irreparable harm, and if there were, that presumption

being like all presumptions rebuttable, it would have been rebutted here by Nephew's delay in seeking an injunction and by its grant of licenses, acts incompatible with the emphasis on the right to exclude that is the basis for the presumption in a proper case."); *Rasterops v. Radius, Inc.*, 861 F. Supp. 1479, 1496 (N.D. Cal. 1994); *Am. Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 324-25 (S.D.N.Y. 1994). Because Plaintiffs' delayed more than three weeks from the time the '672 patent issued and three years from the time Plaintiffs could have filed suit under the Hatch-Waxman Act, they cannot seek injunctive relief to protect their Aldara product which is not even covered by the '672 patent.

**6. Plaintiffs' Authority For Its TRO Motion Is Miscited**

Every case cited by Plaintiffs is clearly distinguishable and not on point. First, no case cited by Plaintiffs addresses the situation where the Plaintiffs' do not have a product covered by the patent in suit. Second, no case cited by Plaintiffs addresses the situation where the Defendant's product has not just been shipped, but it cannot be recalled and it is already in the hands of patients, who are using it for medical treatments that should not be interrupted. (Klaum ¶ 13).

Plaintiffs misrepresents that there is a presumption of irreparable harm. The Court of Appeals for the Federal Circuit established that there simply is no such presumption. *Automated Merchandising Sys., Inc. v. Crane Co.*, 2009 WL 4878643, at *3 (Fed. Cir. Dec. 16, 2009).

**7. Graceway Cannot Post A Bond To Cover Nycomed's Losses**

Graceway's assertions to support a claim of irreparable injury establish that it cannot obtain the required bond for a TRO. Graceway's own Exhibit D shows that lenders have been avoiding it for a while now. And Nycomed's 180 day exclusivity

alone is worth [redacted] to Nycomed, an amount Graceway tacitly admits it cannot obtain a bond. (Klaum ¶ 21).

**C. Defendant Nycomed Will Succeed On The Merits**

Plaintiffs cannot establish a reasonable likelihood of success on the merits. The '672 patent is invalid because it is obvious in view of the prior art, including 3M's prior printed publications and products. (Banker ¶¶ 26-33). Further, the claims and the specification of the '672 patent fails to comply with 35 U.S.C. § 112 written description and enablement requirements. (*Id.* at ¶¶ 19-25; Romito ¶¶ 5-13). "[I]f the accused infringer 'raises a substantial question concerning validity, enforceability, or infringement (i.e., asserts a defense that [the movant] cannot show 'lacks substantial merit') the preliminary injunction should not issue.'" *Altana Pharma,* 566 F.3d at 1006 (citations omitted). Additionally, and importantly, Nycomed's imiquimod cream does not infringe the claims. Thus, Plaintiffs' request for a preliminary injunction should be summarily denied.

**1. The Asserted Patent Is Invalid As Obvious**

The '672 patent is invalid for each of the reasons asserted below. Plaintiffs cannot carry their burden to show that Nycomed's asserted invalidity arguments lack substantial merit, and thus are not entitled to a temporary restraining order or preliminary injunction. *Altana Pharma,* 566 F.3d at 1005-06. "Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." *Erico*, 516 F.3d at 1355-56.

Prior to filing the '672 patent application, imiquimod was a known compound with known formulations. The Chollet Article provides a full report of the work

performed at 3M Pharmaceuticals prior to 1999 to develop a topical cream for imiquimod. (Banker ¶¶ 26-33, Ex. C, p. 35, Abstract). The Chollet Article examines and reports the various different ingredients such as solvents, surfactants, preservatives, and viscosity-enhancing excipients that were commonly used to develop a cream formulation for imiquimod. (Banker ¶ 26; Ex. C, p. 35, Abstract). More specifically, the Chollet Article reported that oleic acid is a well known solvent/solubilizing agent for topical formulations such as creams and that oleic acid was the best solvent for dissolving imiquimod. (Banker ¶¶ 27-28).

The Chollet Article chose isostearic acid as the solvent for use with imiquimod because it "has the fluidity and solubilizing properties of oleic acid" and yet was "the most resistant grade to oxidative degradation and had the lightest color and least odor." (*Id.*, Ex. C, p. 39, left column). In other words, oleic acid would be the best solvent choice in an imiquimod cream formulation but for certain properties such as its oxidative tendency, color and undesirable odor. (*Id.* ¶ 29). However, shortly after the Chollet Article, in 2002, Super Refined Oleic Acid ("SROA") was developed. SROA is an oleic acid which has been further refined or purified, resulting in a "nearly colorless product with a low Peroxide value." (CRODA, p. 1). In other words, SROA is simply a more pure oleic acid and has notably lower peroxide levels (i.e., has less impurities) and is colorless. (Banker ¶ 30).

Accordingly, one of ordinary skill in the art as of December, 2004 would recognize that (a) since the Chollet Article teaches that oleic acid is the best solvent for dissolving imiquimod, and (b) SROA is a highly purified and chemically stabilized form of oleic acid that overcome the oleic acid problems identified in the Chollet Article (i.e.,

SROA has no color, has less impurities, has less oxidative degradation). (Banker ¶¶ 26-33). Thus, it would be clearly obvious to a person of ordinary skill in the art to substitute Super Refined Oleic Acid in place of the older oleic acid solvent that was used in the Chollet Article. (Banker ¶ 32; *also* Palmieri ¶ 5d); *Aventis Pharma Deutschland v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007) ("if it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is prima facie obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified").

Furthermore, one of ordinary skill in the art would have a reasonable expectation that substituting the more pure Super Refined Oleic Acid for the older oleic acid used in the Chollet Article would be successful, especially since the SROA has been stabilized by two mechanisms (i.e., reduction in peroxide levels, addition of BHT antioxidant). This not only makes SROA more stable, but also makes it more compatible with drug substances thereby overcoming the potential limitations of the older oleic cited in the Chollet Article. As such, it is not surprising that substituting the more pure Super Refined Oleic Acid for the oleic acid used in the Chollet Article resulted in a more stable and purer imiquimod cream formulation. (Banker ¶ 33). Therefore, the '672 Patent claims 1-20 are all invalid under 35 U.S.C. § 103 over the combination of the Chollet Article in view of SROA. 566 F.3d at 1007 (obviousness can be shown where "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship … to create an expectation,' in light of the totality of the prior art that the

new compound will have ***'similar properties'*** to the old.'") (emphasis added), (quoting *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990)(en banc)).

Plaintiff may argue that the results of the claimed invention are surprising. The results are in Table II of the patent. However, the reported results do not show any benefit of the invention. The results do not show that the invention led to any stability of the creams over time. (Romito ¶ 13). Therefore, there simply is no invention here.

Plaintiff may also argue that these prior art references relied on by Nycomed were previously considered by the U.S. Patent and Trademark Office ("PTO") and therefore likely to fail. These arguments have been squarely rejected by the Federal Circuit. In *Erico International* the Federal Circuit reversed the district court's grant of a preliminary injunction where the district court held that the defendant's obviousness defense would likely fail because it relied on prior art considered by the PTO. 516 F.3d at 1354-55.

In addition, the combination of the Chollet Article and SROA was never made by the Examiner, who simply missed the point. Even though a patent is presumed valid and deferential weight is given to a prior art that was previously considered by a Patent Examiner during the prosecution of a patent application, these presumptions do not apply with the same force to the '672 patent. Unlike a patent that has undergone substantive examination over a normal time frame, the examination of the '672 patent was extraordinarily short and the most relevant prior art was never truly considered by the Examiner since it was buried among over 150 cited prior art references that had to be reviewed in that extraordinarily short time. (Colucci, Exs. 8-9). As such, no deference should be applied to any prior art that was allegedly considered by the Examiner but not referenced in any office action.

According to the USPTO statistics for the patent applications in this field of technology (i.e., biotechnology and organic chemistry), the average time for a first office action to issue is 22.5 months.[2] Indeed, the first office action in the '672 parent application (U.S.S.N. 11/276,324) did not issue until almost 43 months after it was filed (40 months if counting the time to a Restriction Requirement). (Colucci Exs. 10-11). Yet, the first office action issued in the '672 patent application in less than 4 months by the same Examiner – far shorter than what would normally ensue. (Colucci Ex. 14). And the '672 patent issued in only 14 months – again, far shorter than what it would normally take for a first office action to issue in a normal prosecution.

The reason behind the brief examination is due to Graceway's Petition To Make Special which requested an accelerated examination of the '672 patent application. (*Id.*) However, the speed at which the '672 patent application underwent examination also underscores the lack of true consideration given to all of the prior art, especially since over 150 of them were submitted to the Examiner for consideration. Indeed, the Examiner did not even bother to initial all of the prior art that was submitted in the Information Disclosure Statement – a simple requirement for proving that each individual prior art was indeed considered by the Examiner. (*Id.* Exs. 8-9). Rather, the Examiner only noted at the bottom of the IDS that all references were considered unless lined though. Such notation is insufficient as proof that the Examiner considered the most relevant prior art such as the Chollet Article. (*Id.*) Rather, it is proof that the Examiner did not have enough time to consider all references properly, resulting in a weak patent that contained problematic claims.

[2] http://www.uspto.gov/patents/stats/patentpendency.jsp.

Indeed, Graceway must have known this, otherwise it would not have filed 27 new applications during the 4 days before the '672 patent issued. (Colucci Ex. 1). That number alone is telling. The staggering number is further evidence that the '672 patent has undergone a deficient examination and cannot be entitled to any deference.

**2. The Asserted Patent Is Invalid For Failing To Comply With The Written Description And Enablement Requirements of 35 U.S.C. § 112, Par. 1**

The '672 patent does not contain a proper written description of the invention as required under 35 U.S.C. §112. (Banker ¶¶ 19-25). The '672 patent specification does not (but must, if valid) clearly convey the information the applicants have invented the claimed subject matter. *In re Barker*, 559 F.2d 588, 592 n.4 (C.C.P.A. 1977). Further, the '672 patent does not put the public in possession of what the applicant claims as the invention. *See Regents of the Univ. of California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). The Federal Circuit has stated that the "purpose of [the written description requirement] is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 (Fed. Cir. 2000).

The '672 patent specification fails to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1 because it does not describe or teach anywhere the "imiquimod-related impurities" limitation required in all of the '672 patent claims. (Banker ¶ 19). Rather, the '672 patent specification only teaches one of ordinary skill in the art to test for all of the impurities present in the sample formulations. (Banker ¶ 21).

The '672 patent also fails to comply with a separate enablement requirement of 35 U.S.C. §112, ¶ 1, which requires that the patent specification enable a skilled artisan to

make and use the invention (the "enablement requirement"). In other words, the specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298 (Fed. Cir. 2001), citing *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361 (Fed. Cir. 1997).

The '672 patent claims all include "imiquimod-related impurities" as low as 0.01% or 0.001% or even zero (0) percent. However, the '672 patent specification does not teach anywhere how to achieve a formulation with "imiquimod-related impurities" as low as 0.01% or 0.001% or even zero (0) percent. (Banker ¶¶ 24-25). Therefore, the '672 patent specification does not teach a person of ordinary skill in the art how to practice the full scope of what is claimed in the '672 patent claims. (Banker ¶¶ 9, 25; Palmieri ¶ 5c). *Maytag Corp. v. Electrolux Home Prods.*, 448 F. Supp. 2d 1034, 1080 (N.D. Iowa 2006) (the scope of patent claims must be less than or equal to the scope of the enablement and where the specifications did not teach those of ordinary skill in the art how to "substantially eliminate" a structure, claims were held invalid).

Along these same lines, the courts have found that patent claims relating to the purity of chemical compounds cannot be claimed so broadly that they go beyond what is actually taught in the specifications. *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970).

**3. Defendant Nycomed's FDA Approved Product Does Not Infringe The Asserted Patent**

Determination of patent infringement requires a two step analysis. First, the Court must ascertain the meaning and scope of the claims. *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). Second, the properly construed claims must be compared to the allegedly infringing product. For

example, the patent claims of '672 require certain reduced amounts of impurities after about 15 days (claims 1-6), two months (claims 7-12) and four months (claims 13-20). There can be no basis for a charge of infringement unless these values are measured, and Plaintiffs admit they have not done the test.

Plaintiffs have the burden of proving infringement. Here, their entire case is based on their argument to the Court that Nycomed must be using what they assert is the best oleic acid available and Nycomed's product would get the best results possible if it were ever tested. Plaintiffs have no support for these assertions. In fact, Plaintiffs made the opposite assertions to the FDA in its August 28, 2009 petition to stop Nycomed's approval to market. (Colucci Ex. 3). There, Plaintiffs contradicted the arguments they make here and argue that Nycomed's product with oleic acid is inferior and it should not be approved without extensive testing (e.g., page 1, "the proposed uses of oleic acid raise potential safety risks"). *Id.* Plaintiffs infringement allegations must fail because they are inconsistent with what its scientists told the FDA.

In addition to the above, Nycomed raised the Rule 11 issue that arose from the Plaintiffs' failure to perform a pre-suit investigation with counsel for Plaintiffs. Nycomed served but did not file its motion according to the rules (Rule 11(c)), requesting Plaintiffs to withdraw their baseless allegations, starting the 21 day review period. Plaintiffs report on this process in their motion (page 4) and attempt to criticize Nycomed without providing the actual papers. For purposes of clarity and fairness, Nycomed believes the Court should review the motion papers and Plaintiffs' response and will provide copies if requested at the TRO hearing. For the reasons set forth in these papers,

Plaintiffs' motion for a TRO fails because there is absolutely no proof, no basis, and no good faith belief to support a charge of infringement.

**D. Balancing The Hardships Favors Nycomed**

Balancing the hardships involves balancing "the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted." *Hybritech, Inc. v. Abbott Lab.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). *See Novo Nordisk A/S v. Pfizer Inc.*, No. 06 Civ. 5819(LBS), 2006 WL 3714312, at *6 (S.D.N.Y. Dec. 14, 2006) (citing *Hybritech*, 849 F.2d at 1457). In assessing the balance of hardships, courts consider a variety of factors such as (1) whether the allegedly infringing product is already on the market and would have to be recalled, (2) whether the alleged infringer would be forced to irretrievably forego valuable sales of its generic product, (3) the alleged infringer's monetary investment in developing product and bringing it to market, including the training of sales personnel; and (4) loss of jobs if an injunction is issued. *See, e.g., Novartis Pharms. Corp. v. Teva Pharm. USA, Inc.*, Civ. Action No. 05-CV-1887 (DMC), 2007 U.S. Dist. LEXIS 65792, at *42 (D.N.J. Sept. 6, 2007)(district court considered loss of profits generic might have earned on sales in balancing hardships); *Novo Nordisk*, 2006 WL 3714312, at *6 (court considered development costs for product and training sales persons and doctors for future prescribing of product in balancing hardships); *Cordis Corp. v. Boston Scientific Corp.*, 99 Fed. Appx. 928, 935 (Fed. Cir. 2004) (district court did not err in considering loss of jobs alleged infringer would suffer in balancing hardships).

Here, the balance of hardships is clearly in Nycomed's favor. Nycomed submitted an ANDA for a generic version of Imiquimod Cream 5% in 2006, and served

Graceway with a Paragraph IV notice letter in January 2007. (Klaum ¶ 6). When Graceway did not file a lawsuit under the provisions of the Hatch-Waxman Act, Nycomed invested large sums of money, time and resources, including significant research and development, pre-clinical testing, comparability and bioequivalency testing to obtain FDA approval of its generic product. (*Id.* ¶ 15). Nycomed has already invested [redacted] in readying its generic Imiquimod cream for commercial launch, including, *e.g.*, raw materials and components, clinical development and trial, warehousing. (Klaum ¶ 15). Nycomed's [redacted] does not even include internal overhead and facilities costs spent in readying Nycomed's product for commercial launch. Klaum Decl. ¶ 15.

Upon receiving FDA approval of its ANDA, Nycomed commercially launched its product and began marketing, distributing and selling its generic Imiquimod cream. (Klaum ¶¶ 12-13). As of February 25, [redacted] of the new less expensive generic cream have already been distributed, which amounts to [redacted] gross sales. (*Id.* at ¶ 16). It is Nycomed's understanding that its generic version of Imiquimod cream was available in pharmacies as of February 26, and it is already be in the hands of patients. (Klaum ¶ 13). The cost of Nycomed's generic imiquimod cream is [redacted] than Graceway's Aldara product and is expected to result in substantial savings to patients and Medicare and Medicaid. (*Id.* at ¶ 15).

If Nycomed were enjoined from selling its generic imiquimod cream, the damage to Nycomed and its employees would be devastating. Not only would Nycomed lose [redacted] that it has already invested in developing its imiquimod cream for commercial launch, [redacted]

[redacted]. (Klaum ¶¶ 17-18). Forcing Nycomed to suspend sales of its imiquimod cream would also [redacted]. (Klaum ¶ 19).

Enjoining Nycomed from marketing and selling its generic imiquimod cream would also cause Nycomed to lose the 180-day generic marketing exclusivity granted to it by the FDA according to statute. (Klaum ¶ 20). Nycomed has estimated that the loss of this 180-day exclusivity would cause it to [redacted] in sales in just six months. (Klaum ¶ 20).

Setting aside the debilitating monetary damages that Nycomed would incur if enjoined from selling its generic Imiquimod cream, Nycomed's reputation would also be severely damaged (particularly since Nycomed is currently selling this product to its top customers) if it were suddenly forced to pull its biggest generic dermatological product off the market. (Klaum ¶ 19).

Weighed against the fact that Graceway has already enjoyed the maximum patent protection for its imiquimod cream, Aldara, to which it is entitled by law and the fact that Graceway does not even have a product covered by the '672 patent, Nycomed stands to lose far more than Graceway if it is enjoined from selling its FDA-approved product.

**E. Denying Graceway's Request For A Preliminary Injunction Or Temporary Restraining Order Protects The Public Interest**

While the Hatch-Waxman Amendments seek to balance the competing public interests in increased access to generic drugs and in expanded development of new and valuable medicines (*see* H.R. No. 98-857, pt. 1), that balance tips in favor of the alleged

infringer when the patentee fails to practice its own patented invention. In such situations, courts have exercised their discretion to deny injunctive relief in order to protect the public interest. *See, e.g.*, *Novo Nordisk*, 2006 WL 3714312, at *6 (enjoining release of the first inhalable insulin product when Pfizer's product was more than four years away from reaching the market would be contrary to the public interest); *Hybritech, Inc. v. Abbott Lab.*, 4 USPQ2d 1001, 1016 (C.D. Cal. 1987), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988) (public interest required that injunction not stop supply of medical test kits that neither the patentee nor its licensees were making or marketing). *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548 (Fed. Cir. 1995) (recognizing that courts may exercise their discretion to deny injunctive relief where a patentee's failure to practice its invention "frustrates an important public need for the invention").

As discussed above in Section III(B)(1), Plaintiffs do not make or sell any product covered by the '672 patent. Moreover, to best of Nycomed's understanding, Plaintiffs have not taken any steps to make a product that would be covered by the '672 patent (i.e., Plaintiffs have neither filed a request for an ANDA or NDA with the FDA). Accordingly, the public interest is served in this case by making Nycomed's newly approved lower-cost generic product available to consumers.

**F. Graceway Is Estopped From Benefitting From Its Wrongful Conduct**

A preliminary injunction for patent infringement is an equitable remedy and should be denied where the party has not acted equitably. Plaintiffs have not acted equitably and in fact, are estopped from asserting their infringement claims.[3]

[3] "Estoppel is an equitable defense to a charge of patent infringement and, if proven, may entirely bar an infringement suit." *Id.* (quoting *ABB Robotics, Inc. v. GMFanuc Robotics Corp.*, 52 F.3d 1062, 1063 (Fed. Cir. 1995); *Adelberg Laboratories, Inc. v. Miles, Inc.*, 921 F.2d 1267 1272-73 (Fed. Cir. 1990)). In other words, if the defense of equitable estoppel is successful, the asserted patent(s) are unenforceable as against

There are three elements to an estoppel claim:

(1) the patentee, through misleading conduct, leads the alleged infringer to reasonably infer that it does not intend to enforce the patent against the alleged infringer;

(2) the alleged infringer relies upon the patentee's conduct;

(3) due to the reliance, the alleged infringer will be materially prejudiced if the patentee is permitted to proceed with its infringement suit.

*ABB Robotics, Inc. v. GMFanuc Robotics Corp.*, 53 F.3d 1062, 1063 (Fed. Cir. 1995. With respect to prong one, the "misleading conduct" by the patentee may also take the form of inaction or silence, if the patentee had a clear duty to speak or such silence was accompanied by some other factor indicating that the silence was sufficiently misleading to amount to bad faith. *Id.* at 1064; *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1042-44 (Fed. Cir. 1992). (Klaum ¶¶ 9-10). Specifically, inaction "combined with other facts respecting the relationship or contacts between the parties" may "give rise to the necessary inference that the claim against the [alleged infringer] is abandoned." *ABB Robotics*, 52 F.3d at 1064 (quoting *A.C. Aukerman*, 960 F.2d at 1042); *see also Scholle Corp. v. Blackhawk Molding Co.*, 133 F.3d 1469, 1472 (Fed. Cir.1998) ("[W]hen the course of dealings between a patentee and an alleged infringer is such that the alleged infringer reasonably infers from the patentee's misleading conduct or inaction that the patentee has waived its patent rights, then the first element of equitable estoppel has been established absent a statement to the contrary by the patentee.)

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the alleged infringer – *i.e.*, "bars an injunction or damages for infringement." *Stryker Corp. v. Zimmer, Inc.*, 741 F. Supp. 509, 512 (D.N.J. 1990) (citing *Jamesbury Corp. v. Litton Indus. Prod., Inc.*, 839 F.2d 1544, 1551 (Fed. Cir. 1988)). Similarly, "Laches is an equitable defense which, if successful, bars recovery of damages for infringement which occurred prior to the filing of suit." *Id.*; *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1028-29 (Fed. Cir. 1992).

On January 10, 2007, when Nycomed sent Graceway a letter notifying Graceway of the filing of an ANDA application for the manufacturing a generic version of the product Imiquimod-Aldara®, Plaintiffs "knew, or in the exercise of reasonable diligence should have known, of the alleged infringing activity," *Stryker*, 741 F. Supp. at 512; *see also H.G. Shopping Centers, L.P. v. Birney*, No. H-99-0622, 2000 WL 33538621, at 5 (S.D. Tex 2000). (Klaum, Ex. D). "Plaintiff's undue delay in seeking an injunction 'is an important factor bearing on the need for a preliminary injunction.'" *Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of GE Co.*, 275 F. Supp. 2d 850 (E.D. Mich. 2003) (quoting *High Tech Med. Instrumentation*, 49 F.3d at 1557). In situations similar to the present dispute, the courts often find patents unenforceable because of equitable estoppel or laches, and denied relief of preliminary injunctions or permanent injunctions and/or damages based on alleged patent infringement claims. For example, in *Scholle*, the plaintiff knew of the defendant's allegedly infringing device for three and half years prior to filing suit and over the course of that period, the alleged infringer's sales and marketing of the allegedly infringing device were open and notorious and sales increased. *Scholle*, 133 F.3d 1470-71. The patentee never threatened suit or otherwise raised the issue of infringement. *Id.* Consequently, the *Scholle* court ruled that the patentee's silence in these circumstances constituted misleading conduct which satisfied the first element of the equitable estoppel defense, therefore, affirmed the finding of summary judgment for the defendant on the ground of equitable estoppel. *Id.* at 1472.

In *Electromotive*, the court found that patentee Electromotive Division of General Motors ("EMD") had ample evidence of supposed infringement from its own due diligence during the 1995, 1997 and 1999 negotiations as well as defendant Engine

System's questions regarding the existence of any patents, and strategically remained silent regarding potential patent infringement in order to obtain an upper hand in negotiations. *Electromotive*, 275 F. Supp. 2d at 860. Only after Engine System was acquired by GE and "in essence, it has become worthwhile to enforce its patents, EMD wants preliminary injunctive relief." *Id.* The *Electromotive* court found that EMD's delay mitigates heavily against any finding that it will be irreparably harmed by waiting for a full trial on the merits of its claims. *Id.* at 863. Therefore, the *Electromotive* court denied EMD's motion for preliminary injunctive on equitable estoppel grounds. *Id.*

Similarly, in *Stryker*, this Court estopped the patentee based on its silence in the face of open and notorious "infringement," where the patentee met with the alleged infringer repeatedly over the course of years and was well aware of its allegedly infringing activities for over four years. *Stryker*, 741 F. Supp. at 512-513.

Here, Nycomed expressly notified Plaintiffs of the filing of an ANDA application for the manufacturing a generic version of Aldara more than three years prior to Plaintiff's filing of this motion for preliminary injunction. (Klaum ¶¶ 8-9, Ex. D). Nycomed's application activities to the FDA are open and notorious and the communications are posted on the FDA's official website. Plaintiffs cannot deny the knowledge of potential infringe activities of the asserted patent. For years after this notice, Plaintiffs chose remain silent and not to challenge Nycomed's Paragraph IV statement in the forum specifically provided by the Congress for this purpose under the Hatch-Waxman Act, or notified Nycomed of potential infringement of the pending claims specifically designed to match Nycomed's product under development. Based on the transactions between the parties, Plaintiffs had a duty to inform Nycomed of the existence

of this pending application. *See Forest Labs. v. Abbott Labs.*, No. 96-CV-159-A, 1999 WL 33299123 (W.D.N.Y June 23, 1999) at *22, 25. Yet Plaintiffs remained silent, "until there was a plum ripe enough to be plucked," *i.e.*, until Nycomed has relied on Plaintiffs' silence and invested larges sums of money, time and resources, including significant research and development; pre-clinical testing, comparability and bioequivalency testing to obtain approval of the ANDA and "render[ed] it worthy of suit." *Stryker*, 741 F. Supp. at 515.

Plaintiffs' inaction and silence induced and unfairly misled Nycomed into believing that Plaintiffs had no intention to enforce any patent claims against Nycomed. (Klaum ¶¶ 8-10). This amounts to bad faith. Nycomed relied to its detriment on this affirmatively misleading conduct and due to the reliance, Nycomed will be materially prejudiced if the patentee is permitted to proceed with its infringement suit. Further, Plaintiffs' unreasonably and inexcusably delayed in enforcing its patent against Nycomed and Nycomed was materially prejudiced by that delay. Plaintiffs' motion for preliminary injunction should be denied as Plaintiffs' asserted patent is unenforceable under the doctrines of equitable estoppel and laches.

## IV. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for a TRO must be denied.

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By: /s/ Albert B. Chen

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